CLAIMS

We claim:

1. A medical device for delivering a biologically active material to a body tissue of a patient in need of treatment, wherein the medical device comprises a plurality of struts and a plurality of non-structural elements integral with the struts, wherein the struts and the non-structural elements comprise the biologically active material.

2. The medical device of claim 1, wherein the non-structural elements project from the struts and are configured in a shape selected from the group consisting of a cone, a truncated cone, an oval, a straight rod, a bent rod, and a rod having heads at the ends.

3. The medical device of claim 1, wherein the non-structural elements are configured in a shape selected from the groups consisting of hoops, knots and bends, which are located along the stents.

4. The medical device of claim 1, which comprises a tubular portion comprising an outer surface, and wherein the non-structural elements are distributed throughout the outer surface.

5. The medical device of claim 1, which comprises a tubular portion comprising an outer surface, wherein the non-structural elements are located in a radially asymmetric distribution on the outer surface.

6. The medical device of claim 5, wherein the non-structural elements are distributed in a rectangular portion of the outer surface.

7. The medical device of claim 6, wherein the rectangular portion is parallel to longitudinal axis of the tubular portion.

8. The medical device of claim 7, wherein the rectangular portion and the tubular portion have same length.

9. The medical device of claim 8, wherein the surface area of the rectangular portion is from about 25% to about 75 % of the entire surface area of the outer surface.

10. The medical device of claim 1, which comprises a tubular portion comprising an outer surface, wherein the outer surface has a middle section and end sections, and wherein the end sections comprise a greater number of the non-structural elements per unit length of the outer surface than the middle section.

11. The medical device of claim 1, wherein the biologically active material is selected from the group consisting of paclitaxel, actinomycin, sirolimus, tacrolimus, everolimus, dexamethasone, halofuginone and hydrophobic nitric oxide adducts.

12. The medical device of claim 1, the medical device is a stent.

13. A method for designing a medical device for delivering a biologically active material to a body tissue of a patient, wherein the medical device comprises a plurality of struts and a plurality of non-structural elements integral with the struts, wherein the struts and the non-structural elements comprise the biologically active material, wherein the method comprises:

(a) providing a preliminary medical device comprising a plurality struts in a geometric pattern wherein the struts comprise the biologically active material;

(b) determining a concentration-profile for the biologically active material which is released from the preliminary medical device; and

(c) modifying the geometric pattern of the struts of the preliminary medical device by incorporating a plurality of non-functional elements comprising the biologically active material that are integral with the struts to achieve more desired distribution of the biologically active material in the body tissue.

14. The method of claim 13, wherein the biologically active material has a minimum effective concentration and a maximum effective concentration for the body tissue, and wherein steps (b) and (c) are repeated until the body tissue to be treated is substantially free from a concentration of the biologically active material that is smaller than the minimum effective concentration and a concentration of the biologically active material that is greater than the maximum effective concentration over a desired time period.

15. The method of claim 13, wherein the biologically active material is selected from the group consisting of paclitaxel, actinomycin, sirolimus, tacrolimus, everolimus, dexamethasone, halofuginone and hydrophobic nitric oxide adducts.

16. The method of claim 13, wherein the medical device is a stent.

17. A medical device insertable into the body of a patient, which comprises an outer surface comprising a plurality of struts, wherein the outer surface has a middle section and end sections, and wherein the end sections have a greater available surface area per unit length of the outer surface than the middle section.

18. The medical device of claim 17, wherein at least a part of each of the middle section and the end sections of the outer surface comprise the biologically active material.

19. The medical device of claim 17, wherein struts located at the end sections have a greater surface area by having a more porous surface than struts located at the middle section.

20. The medical device of claim 19, wherein the struts located at the end sections are comprised of a porous material and the struts located at the middle section is comprised of a less porous material.

21. The medical device of claim 20, wherein the struts located at the end sections are covered with the porous material, and the struts located at the middle section are covered with the less porous material.

22. The medical device of claim 17, wherein the average diameter of the struts located at the end sections is greater than the average diameter of the struts located at the middle section.

23. A medical device insertable into the body of a patient, which comprises an outer surface comprising a plurality of struts, wherein the outer surface has a middle section and end sections, and wherein the end sections a greater affinity for the biologically active material area per unit length of the outer surface than the middle section.

24. The medical device of claim 23, wherein at least a part of each of the middle section and the end sections of the outer surface comprise the biologically active material.

25. The medical device of claim 23, wherein the struts located at the end sections

comprise a first matrix material and the struts located at the middle section comprise a second matrix material, and wherein the first matrix material has a greater affinity for the biologically active material than the second matrix material.

26. The medical device of claim 25, wherein the struts located at the end sections are covered with a coating of the first matrix material and the struts located at the middle section are covered with a coating of the second matrix material.

27. The medical device of claim 25, wherein the end sections and middle section further comprise the biologically active material.

28. The medical device of claim 23, wherein at least a part of each of the middle section and the end sections are covered with a linking material, and wherein the struts located at the end sections comprise a greater amount of the linking material per unit length of the outer surface than the struts located at the middle section.

29. The medical device of claim 28, wherein the outer surface comprises the biologically active material which is linked to the linking material.

30. The medical device of claim 19, which the medical device is a stent.

31. A medical device insertable into the body of a patient, which comprises an outer surface, wherein the outer surface has a middle section and end sections, wherein at least a part of each of the middle section and the end sections is covered with a coating layer comprising a first biologically active material, and wherein the end sections carry or contain a larger amount of first biologically active material per unit length of the outer surface than the middle section.

32. The medical device of claim 31, wherein the medical device comprises a tubular portion that comprises the outer surface.

33. The medical device of claim 31, wherein the coating covering the end sections comprises a coating layer containing a second biologically active material.

34. A medical device insertable into the body of a patient, which comprises an

outer surface, wherein the outer surface has a middle section and end sections, wherein at least a part of each of the middle section and the end sections is covered with a coating comprising a first biologically active material, and the middle section comprises a barrier layer placed over the coating covering the middle section for reducing the release rate of the biologically active material.

35. The medical device of claim 34, wherein the medical device comprises a tubular portion and the outer surface is at least a part of the outer surface of the tubular portion.

36. The medical device of claim 35, wherein the medical device is a stent and the barrier layer is a sheath.

37. A medical device insertable into the body of a patient , which comprises an outer surface comprising a plurality of struts, wherein the outer surface has a rectangular portion having a greater capacity for carrying or containing a biologically active material per unit length of the outer surface than the parts of the outer surface that are outside the rectangular portion, by having a greater surface for carrying or having a greater affinity for the biologically active material than the parts of the outer surface that are outside the rectangular portion.

38. The medical device of claim 37, wherein the medical device comprises a tubular portion comprising the outer surface, and the rectangular portion is parallel to longitudinal axis of the tubular portion.

39. The medical device of claim 38, wherein the rectangular portion and the tubular portion have same length.

40. The medical device of claim 39, wherein a surface area of the rectangular portion is from about 25% to about 75 % of the outer surface.

41. The medical device of claim 37, wherein at least a portion of the outer surface comprises the biologically active material.

42. The medical device of claim 37, wherein the medical device is a stent

43. A method for delivering a biologically active material to body tissue of a patient in need of treatment which comprises inserting a medical device of claim 38 into body of the patient in such a way that the rectangular portion is in direct contact with the body tissue in need of treatment.

44. The method of claim 43, wherein the biologically active material is selected from the group consisting of paclitaxel, actinomycin, sirolimus, tacrolimus, everolimus, dexamethasone, halofuginone and hydrophobic nitric oxide adducts.